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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/785,606

02/23/2004

Nadine Voigt

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EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
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1617

NOTIFICATION DATE	DELIVERY MODE
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06/25/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<p align="center">Office Action Summary</p>	Application No. 10/785,606	Applicant(s) VOIGT ET AL.	
	Examiner Gina C. Yu	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/23/04, 4/3/06</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Evaluating enablement requires determining whether any undue experimentation is necessary for a skilled artisan to determine how to make and/or use the claimed invention. Factors to be considered in determining whether any necessary experimentation is "undue" include, but are not limited to: 1) the breadth of the claims; 2) the nature of the invention; 3) the state of the prior art; 4) the level of one of ordinary skill; 5) the level of predictability in the art; 6) the amount of direction provided by the inventor; 7) the existence of working examples; and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See In re Wands, 858 F.2d 731, 737, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988).

the nature of the invention: the claims encompass using a composition which merely requires a combination of acrylic acid gelling polymers, cosmetic lipids, one or

more emulsifiers and fatty alcohols to treat oily skin, blemishes and acne; and to decorate skin.

3) the state of the prior art: the state of the prior art does not recognize that the rheological components of instant claim 17 by themselves effectively treats oily skin or blemishes and acne, or to decorate skin, without any aid of additional functional ingredients. See Favre (US 6395262 B1), which requires fillers and/or pigments to make a matte or make-up compositions.

4) the level of one of ordinary skill: the testing of the efficacy of the claimed invention would require one ordinary skill in dermatology, particularly in acne treatment, for claim 22, and cosmetic art, for claim 22.

5) the level of predictability in the art : based on the teachings of the functions of the recited components of the claimed composition, it is highly unpredictable that the composition as recited in claim 17 alone will treat oily skin, blemishes or acne or effectively make-up the skin.

6) the amount of direction provided by the inventor: the only direction provided by the inventor in the specification regarding the method of claim 20 is found on p. 5, lines 20 and 21, that the present invention is "characterized by better care, in particular of greasy skin which is prone to pimples and acne". While the inventor describes the present preparations as "a very good vehicles" for cosmetic or dermatological active ingredients, there is no direction or guidance that the compositions without any active ingredients will treat greasy skin, acne or blemishes. Similarly, there is no direction or guidance as to how to use the composition of claim 1, which contains no decorative

cosmetic ingredients, to practice the method of claim 22, unless active ingredients are added to the composition.

7) the existence of working examples; There is no working example in the specification which demonstrates treating greasy skin, acne, or blemishes, or decorating the skin, with the preparations of claim 1, which contains no active ingredients other than thickeners, surfactant(s), oil(s) and water.

8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure: The quantity of experimentations needed to make or use the invention is large, at least for claim 20, because the causes of blemish or acne are diverse, such as bacterial infection, food intake, hormonal changes, etc. Furthermore, applicants claim that the invention treats "acne-prone skin". The burden of enabling the treatment of skin which is prone to a condition (i.e., the need for additional testing) would be greater than that of enabling a treatment of an existing condition due to the need to screen those humans susceptible to such conditions.

In the instant case, the specification does not provide guidance as to how one skilled in the art would go about treating greasy skin, blemishes or acne-prone skin and decorating the skin within the scope of the presently claimed invention. Nor is there any guidance provided as to a specific protocol to be utilized in order to prove the efficacy of the presently claimed method in among the subjects. The specification fails to enable the claimed method of claims 20 and 22 and undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed methods.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 18, the term "light skincare product" renders the claim vague and indefinite. It is not clear how "light skincare product" is different from conventional skin care products.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-6 and 9-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Favre et al. (US 6395262 B1) in view of Cosmetic Additives (1991).

Favre teaches in Example 5 an oil-in-water emulsion cosmetic formulation comprising a) 0.6 % by weight of Carbopol 980 from Goodrich, which meets the polyacrylic acid thickener of instant claims 1 and 17 a); b) 0.1 % by weight of Pemulen TR2, also from Goodrich, which meets the acrylic acid/C10-30 alkyl methacrylate copolymer of instant claims 1 and 17 b); c) 8 % by weight of Apricot oil; and 0.1 % of a nonionic surfactant, sorbitan monostearate (20). See instant claims 1-3, 5, 6, 15, 17. Adding fatty alcohols such as stearyl alcohol or cetyl alcohol up to 5 % by weight is taught in col. 9, lines 1 – 6. See instant claims 1 e), 17 e), 9, 10. The reference teaches adding the Carbopol polymers “effectively makes it possible, in particular, to obtain a physically and cosmetically pleasant product, especially one which is smooth and of satisfactory application, with a viscosity which may range from fluid milk to cream”. See col. 9, lines 35 – 44. Based on this teaching, the skilled artisan would have expected that topical application of Example 5, which contains Carbopol 980 in combination of the Pemulen TR2 in the claimed amount, would be pleasant to the skin, which renders the use of instant claims 18 and 19 obvious. Since the reference teaches that the polymer is used to vary the viscosity of the composition, adjusting the weight amount of the polymer by routine experimentation to discover optimum weight amount for a desired viscosity of the formulation would have been obvious to a skilled artisan. See instant claim 4. The reference also teaches adding “one or more” additional

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thickeners such as xanthan gum, celluloses, and polyacrylamide-based polymers up to 6 % by weight. See col. 9, lines 7 – 35; instant claims 11-14. Cosmetic auxiliaries are taught in col. 10, lines 38 – 52. See instant claims 16. The reference also teaches that the compositions are applied in make-up compositions such as foundation by adding pigments. See col. 9, line 58 – col. 10, line 68. See instant claims 21 and 22. Also taught is using fillers to control the matte effect to the make up, which indicates that the composition is also intended to be used for oily skin. See col. 9, lines 51 – 57; instant claim 20.

While Favre generally teaches that surfactants are used to further “refine the emulsion obtained”, the reference fails to mention the surfactants of the instant claims 1 and 17 d).

Cosmetic Additives teaches that triceteareth-4 phosphate is an oil-in-water emulsifier that aids fast absorption of the composition into skin. See p. 354, Hostaphat KW 340 N and Hostacerin CG.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the oil-in-water emulsion of Favre by incorporating triceteareth-4 phosphate, as motivated by Cosmetic Additives, because the latter teaches that the oil-in-water emulsifier aids fast absorption of the composition into skin. The skilled artisan would have had a reasonable expectation of successfully producing an oil-in-water emulsion cosmetic which is rapidly absorbed to the skin.

Claims 1-6 and 9-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Favre and Cosmetic Additives as applied to claims 1-6 and 9-

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22 as above, and further in view of Cosmetic and Toiletry Formulations (1996, 2nd ed., Vol. 5).

The combined references fail to teach the amount by which triceteareth-4 phosphate is used.

Cosmetic and Toiletry Formulations teaches that 1 % of triceteareth-4 phosphate is used in an oil-in-water skin milk formulation comprising 0.15 % of Carbopol 980.

It would have been obvious to the skilled artisan to formulate the composition of the combined references by using triceteareth-4 phosphate according to the teaching of Cosmetic and Toiletry Formulations, because a) Favre teaches that Carbopols are used to make fluid milk formulations and b) Cosmetic Toiletry Formulations teaches a specific example of skin milk oil-in-water emulsion which employs the same polyacrylic acid thickener used in Favre, and the specific amount of triceteareth-4 phosphate to be used. The skilled artisan would have had a reasonable expectation of successfully producing a stable skin milk emulsion which is rapidly absorbed to the skin.

Conclusion

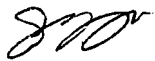
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605. The examiner can normally be reached on Monday through Friday, from 8:00AM until 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Gina C. Yu
Patent Examiner